

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)  
and the Drug Safety and Risk Management Advisory Committee (DSaRM)***

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
August 4, 2016

**QUESTIONS**

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1. **DISCUSSION:** Please discuss whether there are sufficient data to support a finding that Arymo ER (morphine sulfate extended-release tablets) has properties that can be expected to deter abuse, commenting on support for abuse-deterrent effects for each of the three possible routes of abuse:
  - a. Oral
  - b. Nasal
  - c. Intravenous
  
2. **VOTE:** If approved, should Arymo ER be labeled as an abuse-deterrent product by the oral route of abuse?
  
3. **VOTE:** If approved, should Arymo ER be labeled as an abuse-deterrent product by the nasal route of abuse?
  
4. **VOTE:** If approved, should Arymo ER be labeled as an abuse-deterrent product by the intravenous route of abuse?
  
5. **VOTE:** Should Arymo ER be approved for the proposed indication, management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate?